

INTERIM RULEMAKING NOTICE FORM

Proposed Interim Rule Number 2015-10 Rule Number He-P 2205

1. Agency Name & Address:

**Department of Health & Human Services
Division of Public Health Services
Public Health Laboratories Section
29 Hazen Drive
Concord, NH 03301**

2. RSA Authority: RSA 131:4

3. Federal Authority: _____

4. Type of Action:

Adoption X

Amendment _____

Repeal _____

Readoption _____

Readoption w/amendment _____

5. Filing Date: **September 3, 2015**

6. Short Title: **Public Health Laboratories Fee Schedule**

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

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The proposed rules may be viewed and downloaded at:

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Summary explaining the effect of the rule:

He-P 2205 establishes the fees for laboratory tests performed by the Public Health Laboratories (PHL) of the Department of Health and Human Services (DHHS). PHL services include conducting testing related to disease outbreaks, surveillance and other public health events of concern. PHL has a specially equipped facility and trained staff to test for highly infectious diseases such as rabies and tuberculosis, and performs testing of food, such as shellfish to monitor Red Tide events, and dairy products, to assure product safety. The rule allows PHL to effectively administer laboratory services and assess fees for the testing it performs for DHHS programs, state agencies, healthcare providers and others requiring its specialized facilities and staff expertise. In fiscal year 2015, revenue of approximately \$322,369 was generated for the state general fund from fees assessed by PHL for its services. The rule was effective on May 25, 2007 and expired on May 25, 2015. Pursuant to RSA 541-A:19, I(e), the adoption of an interim rule is necessary in order to minimize the time between the expiration of the rule and its subsequent readoption as a regular rule.

9. Listing of people, enterprises, and government agencies affected by the rule:

Those affected by the rule include groups and individuals who rely on PHL testing and are billed according to the fees listed in He-P 2205. Some of the groups affected include DHHS programs for infectious disease control, such as the HIV, STD and TB prevention programs, and other state agencies including the NH Medical Examiner's Office, the Department of Corrections and the NH Estuaries Project. PHL also provides services and bills healthcare providers or others requiring its specialized testing facilities and staff expertise.

10. Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement.

RULE	STATE OR FEDERAL STATUTORY AUTHORITY
He-P 2205	RSA 131:4

11. Summary of the effect upon the state if the rule were not adopted:

The rule is being submitted for adoption as an interim rule in accordance with RSA 541-A:19, I(e) in order to minimize the time between the expiration of existing rule on May 25, 2015 and the subsequent readoption of He-P 2205 as a regular rule. Without the interim rule, PHL will lack the ability to effectively administer laboratory services and assess fees for the testing it performs for DHHS programs, other state agencies, healthcare providers and dairies. In FY 2015, revenue of approximately \$322,369 was generated for the state general fund from the fees assessed by PHL for its services. Without the interim rule, there is potential for a loss of state general fund revenue.

12. Proposed date of review by the Joint Legislative Committee on Administrative Rules:

September 17, 2015.

13. The fiscal impact statement prepared by the Legislative Budget Assistant, if applicable.

Not applicable.

Adopt He-P 2205, previously effective 5-25-07 (Document #8891), and expired 5-25-15, to read as follows:

PART He-P 2205 LABORATORY FEE SCHEDULE

He-P 2205.01 Clinical Specimens, Chemistry. The following fees shall be charged for those clinical specimens set forth in Table 2200.01 Chemistry below:

Table 2200.01 Chemistry

<u>TEST</u>	<u>FEE</u>
Arsenic, blood, quantitative	65.00
Arsenic, urine, quantitative	25.00
Cadmium, urine	50.00/hr.
Copper, serum	50.00/hr.
Copper, urine	50.00/hr.
Creatinine, other source	10.00
Cyanide, blood	40.00
Erythrocyte protoporphyrin, quantitative	10.00
Heavy Metal Screen	50.00/hr.
Lead, blood	22.00
Mercury, blood quantitative	80.00
Mercury, urine, quantitative	80.00
Miscellaneous analysis	50.00/hr

He-P 2205.02 Clinical Specimens, Microbiology. The following fees shall be charged for those clinical specimens set forth in Table 2200.02 Microbiology below:

Table 2200.02 Microbiology

TEST	FEE
Adenovirus – culture	50.00
Adenovirus – immunofluorescent, each antisera	20.00
Bacterial culture, blood, aerobic	28.00
Bacterial culture, urine	28.00
Bacterial culture, other, aerobic	28.00
Bacterial culture, other, anaerobic	28.00
Bacteria, identification, per isolate, aerobic	21.00
Bacteria, identification, per isolate, anaerobic	21.00
Chlamydia culture	50.00
Chlamydia immunofluorescent, each antisera	20.00
Chlamydia trachomatis, amplified method	25.00
Cryptosporidium/Giardia , DFA	35.00
Cryptococcus latex agglutination	25.00
Cytomegalovirus (CMV) culture	50.00
Cytomegalovirus (CMV), immunofluorescent, each antisera	20.00
Diphtheria culture	35.00
Direct smear, simple stain	21.00
Eastern Equine Encephalitis (EEE) Virus Antibodies, IgG	35.00
Eastern Equine Encephalitis (EEE) Virus Antibodies, IgM	35.00
Enteric pathogen culture, stool (single organism)	21.00
Enteric pathogen culture, stool (Salmonella and Shigella)	21.00
Enteric pathogen culture (comprehensive – includes SLT test)	50.00
Enteric isolate for identification, per aerobic isolate	21.00
Enteric isolate for identification, per anaerobic isolate	21.00
Enterovirus culture	50.00
Enterovirus immunofluorescent, each antisera	20.00
Enzyme immunoassay, per specimen	18.00
Fluorescent Antibody Tests, Direct	15.00
Gonorrhea culture	21.00
Hantavirus, IgG and IgM	60.00
Hepatitis A antibody – total	30.00
Hepatitis A IgM antibody	30.00
Hepatitis B surface antigen	30.00
Hepatitis B surface antibody	30.00
Hepatitis B core antibody – total	30.00
Hepatitis B core antibody IgM	30.00
Hepatitis B - other marker	50.00
Hepatitis C antibody screen	30.00
Hepatitis C amplified method	100.00
Hepatitis C RIBA	100.00
Herpes simplex culture	50.00
Herpes simplex immunofluorescent, each antisera	20.00
Herpes simplex DFA, type 1	20.00
Herpes simplex DFA, type 2	20.00
Herpes simplex, type 1 antibody	30.00

Herpes simplex, type 2 antibody	30.00
Human Immunodeficiency Virus -1 (HIV-1), antibody	25.00
Human Immunodeficiency Virus –1 and 2 antibody, single assay	40.00
Human Immunodeficiency Virus (HIV) confirmatory test by Western Blot	50.00
Infectious agent screen – other	35.00
Influenza culture	75.00
Influenza immunofluorescent, each antisera	20.00
Legionella culture	40.00
Legionella DFA	10.00
Legionella referred isolate	40.00
Legionella urinary antigen	25.00
Lyme Disease antibodies ELISA - IgG and IgM	25.00
Lyme Disease confirmatory test by Western Blot, each assay	50.00
Measles (Rubeola) IgG antibody (Immune Status)	25.00
Measles (Rubeola) IgM antibody	30.00
Mumps culture	50.00
Mumps immunofluorescent, each antisera	20.00
Mumps IgG antibody	25.00
Mycobacteria isolate identification	85.00
Mycobacteria (AFB) smear	10.00
Mycobacteria (AFB) smear and culture	45.00
<i>Mycobacterium tuberculosis</i> susceptibility – first line drugs, each drug	25.00
Mycology culture, blood	35.00
Mycology culture, skin, hair or nails	35.00
Mycology culture, other	35.00
Mycology yeast identification, per isolate	50.00
Mycology non-yeast identification, per isolate	50.00
Mycology contaminated isolates (charged in addition to identification fee)	20.00
<i>Neisseria gonorrhea</i> , amplified method	25.00
Parainfluenza culture	50.00
Parainfluenza virus immunofluorescent, each antisera	20.00
Parasitology, blood/tissue parasites	43.00
Parasitology, stool for ova & parasite	89.00
Parasitology, worm Identification	13.00
Parasitology, modified acid fast stain for Cyclospora, Isospora and Sarcocystis	43.00
Parasitology, Microsporidium, modified trichrome blue stain	70.00
Parvovirus B19, IgG and IgM	25.00
Pertussis culture	40.00
Pneumocystis jiroveci (carinii) DFA	35.00
Pulsed field gel electrophoresis (PFGE), per isolate	125.00
Rabies (no public health risk)	175.00
Respiratory virus culture	50.00
Respiratory virus immunofluorescent, each antisera	20.00
Respiratory syncytial virus (RSV) culture	50.00
Respiratory syncytial virus (RSV) immunofluorescent, each antisera	20.00
Respiratory syncytial virus (RSV) DFA	20.00
Rubella antibody, IgG	25.00
Rubella antibody, IgM	30.00

Serogrouping, <i>Shigella</i> species	45.00
Serotyping, <i>Salmonella</i> species	50.00
Serotyping, <i>Neisseria meningitidis</i>	66.00
Serotyping, <i>Haemophilus influenzae</i>	66.00
Serotyping, <i>Vibrio cholera</i> serotyping	45.00
Serotyping, Enterohemorrhagic <i>Escherichia coli</i>	66.00
Shiga-like Toxin screen	40.00
St. Louis Encephalitis virus antibodies, IgG	35.00
St. Louis Encephalitis virus antibodies, IgM	35.00
Susceptibility testing - Kirby Bauer (up to 12 disks)	25.00
Susceptibility testing – E-test, per drug	10.00
Susceptibility testing, fungal, per drug	59.00
Syphilis, qualitative	15.00
Syphilis, quantitative	25.00
Syphilis, confirmatory	30.00
Toxin assay	40.00
Varicella zoster virus culture	50.00
Varicella zoster virus immunofluorescent, each antisera	20.00
Varicella zoster virus DFA	20.00
Varicella zoster antibody	35.00
Virus culture - other	50.00
Virus culture immunofluorescent	20.00
Western Blot, other than HIV	60.00
West Nile Virus (WNV), IgG	35.00
West Nile Virus (WNV), IgM	35.00
Specimen to Reference Lab/CDC	Cost of test plus shipping
Norovirus, PCR	83.00
Influenza A/B, PCR	195.00
Influenza Subtyping, PCR	112.00
<i>Bordetella pertussis</i> , PCR	128.00
<i>Bordetella pertussis</i> positive confirmation, PCR	84.00
<i>Bordetella pertussis</i> diluted repeats, PCR	64.00
Mumps, PCR	105.00
Shiga Toxin (STEC), PCR	91.00
Ribotyping	97.00
Pulsed Field Gel Electrophoresis	154.00
Rep-PCR	158.00
Hepatitis C Virus Genotyping, 3 rd Wave Method	158.00
Hepatitis C Virus Genotyping, Sequencing Method	159.00
MDX - DNA or RNA isolation	6.00
MDX - DNA or RNA purification	15.00
MDX – restriction enzyme digestion, per reaction	6.00
MDX – gel electrophoresis, per lane (reaction)	6.00
MDX – nucleic acid probe, each	6.00
MDX – nucleic acid transfer	6.00
MDX – single PCR amplification	16.00
MDX – duplex PCR amplification	32.00
MDX – multiplex PCR amplification, each additional after duplex	16.00
MDX – reverse transcription	14.00
MDX – cell lysis prior to isolation or purification	12.00

MDX – interpretation and reporting	20.00
MDX – complex separation	20.00
MDX - miscellaneous	75.00/hr

He-P 2205.03 Occupational and Environmental Health Samples. The following fees shall be charged for those occupational and environmental health samples set forth in Table 2200.03 Occupational and Environmental below:

Table 2200.03 Occupational and Environmental

TEST	FEE
Lead or Cadmium - paint, or release from pottery glaze or decorative glasses	25.00
Lead, maple syrup	40.00
Lead, soil, or bioavailable from dust	25.00
Miscellaneous analysis	50.00/hr

Source.

He-P 2205.04 Consumer Protection Samples. The following fees shall be charged for those consumer protection samples set forth in Table 2200.04 Consumer Protection below:

Table 2200.04 Consumer Protection

TEST	FEE
Food - Complete bacterial analysis	100.00
Food - Coliform count, total and fecal, Most Probable Number (MPN)	60.00
Food - Pathogen screen, per organism	40.00
Food - Foreign object	25.00
Food - pH	7.50
Food - Standard plate count	35.00
Food - Complete bacterial analysis, quality only	50.00
Food – Staphylococcus Culture	35.00
Food - Water activity	7.50
Milk or Cream - Complete analysis	25.00
Milk or Cream - Antibiotics, per group	10.00
Milk or Cream - Butterfat content	11.00
Milk or Cream - Coliform count	10.00
Milk or Cream - Direct Microscopic Somatic Cell Count (DMSCC)	18.00
Milk or Cream - Pathogen screen, per organism	40.00
Milk or Cream - Standard plate count	10.00
Milk or Cream - Total solids	8.00
Milk or Cream - Dairy waters	21.00
Milk or Cream - Phosphatase	8.00
Milk or Cream - Vitamin A or D	50.00
Milk or Cream - Added water	10.00
Milk or cream – Container analysis	15.00
Miscellaneous analysis	50.00/hr
Seawaters, complete bacterial analysis	60.00
Seawaters – Fecal coliform	46.00

Seawaters – pH	7.00
Seawaters – Salinity	7.00
Shellfish - Complete bacterial analysis	70.00
Shellfish - Fecal coliform count, (MPN)	60.00
Shellfish - Standard plate count	50.00
Shellfish - Microorganism identification	40.00
Shellfish Toxin Assay (e.g. PSP)	200.00
Toxin assay, misc.	75.00

He-P 2205.05 Addition of Tests to Fee Schedule. Pursuant to RSA 141-C:19 laboratory tests shall be added to the fee schedule if any one or more of the following occurs:

- (a) The test is required by law;
- (b) The test is required to support the work of the division and other state agencies; and
- (c) The test is required to protect the public health of New Hampshire, and is not readily available to other locations within the state.

APPENDIX

RULE	STATUTE
He-P 2205	RSA 131:4